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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,145	01/30/2001	Eilaz Babaev	24149.14	1226

7590

09/24/2003

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 09/24/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,145

Applicant(s)

BABAEV, EILAZ

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/30/01, 4/17/02, 4/26/02, 5/31/02, 8/12/02, 11/4/02, 1/21/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,9-11 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,9-11 and 19-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4, 7, 9
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-3, 6, 9-11 and 19-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claims 1, 9 and 22, the specification fails to teach specific parameters for how the created standing wave/radiation pressure provides a bactericidal and therapeutic effect for decreasing the healing time without undue experimentation - unless the bactericidal/therapeutic/reduced healing time effects are intrinsic properties of the created standing wave/radiation pressure. Regarding claim 6, the specification does not teach how, when, or what gel, drug, or medicament to apply to the wound to achieve therapeutic effects without undue experimentation. Regarding claim 26, the specification does not teach how to dissolve blood clots, etc., in conjunction with providing a bactericidal effect – unless the bactericidal effect is an intrinsic property of the created standing wave/radiation pressure. Regarding claim 27,

the specification does not teach what drug may be successfully penetrated through the surface of the wound using ultrasound standing waves without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6, 11 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, "other medicant" is indefinite in that the scope cannot be ascertained. In claims 11 and 28, it is unclear from the disclosure (i.e., specification and drawings) whether the end of a bushing (or similar type device) must also be separated a distance from the wound.

Claim Interpretation

It is understood from the specification that standing waves occur as a result of (constructive) superposition of incident and reflected ultrasound waves, wherein the distance of occurrence is inherently defined as $n \times \lambda/2$ (page 3, first paragraph).

Since the specification does not indicate otherwise, the examiner assumes for examination purposes that bactericidal/therapeutic/decreased healing time- effects are intrinsic properties of standing waves/radiation pressure applied to a wound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 9-11, 22, 23, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter '663.

Carter teaches a method and apparatus for adjustably creating standing waves traveling from a distal radiation surface of an ultrasound transducer (24) through a guide, or bushing, (44) to a surface of a wound for treatment. See figures 4a and b, col. 2 lines 13-25. Carter further teaches ultrasound frequencies between 50kHz-1.3MHz (col. 6 lines 21-27).

4. Claims 1, 2, 9, 10, 19-25 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. '499 of record

Martin teaches a method and apparatus for treating a wound using focused ultrasound by adjusting the position of a transducer to achieve superposition of incident and reflected waves (i.e., standing waves) at the surface of the wound/target region. See fig. 4B, 6A-C, 11 and 12 and col. 10 lines 22-45. Martin further teaches wherein the ultrasound frequency is 0.5-20MHz and wherein continuous or pulsed energy may be used (col. 9 lines 15-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter or Martin et al. '499 of record.

Regarding claims 3 and 24, Carter and Martin et al. do not explicitly address a distance of at least 0.1", however lacking any criticality, the distance of the created standing waves would have been an obvious matter of design choice to a person of ordinary skill in the art depending upon the particular application.

6. Claims 20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter '663.

Regarding claims 20 and 25, Carter does not address the applied waveform explicitly, however lacking any criticality, the shape of the waveform would have been an obvious matter of design choice to a person of ordinary skill in the art depending upon the particular application.

7. Claims 6 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter in view of Brisken '811 of record.

Regarding claims 6 and 27, Carter differs from the claimed invention in that a drug is not explicitly addressed. Brisken teaches a method and apparatus for enhanced fluid/drug delivery in the removal of intravascular plaque and clots using ultrasound standing waves. See col. 1 lines 57-62 and col. 12 lines 9-28. It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to use a drug such as a thrombolytic agent as taught by Brisken in the invention as taught by Carter to enhance intravascular clot dissolution.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-3, 9-11, 19-25, 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6-10, 13, 14, 16, 18, 20 and 21 of U.S. Patent No. 6,478,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the patent, ultrasound is delivered using standing waves applied at a distance $d = nx \lambda / 2$ (col. 6). Claims 1-3, 9-11, 19-25, 27 are therefore an obvious broadening and/or variation of the patented claims. Furthermore, it would have been obvious to replace the groove or ring of Patent No. 6,478,754 with a bushing since they both provide the same function of increasing the ultrasound radiation pressure.

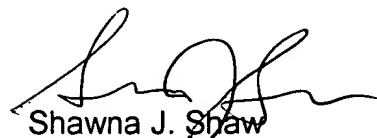
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'Shawna J. Shaw', is written over the printed name.

Shawna J. Shaw
Primary Examiner
9/2/03